Case-control study

A case-control study starts from the outcome, including a sample of patients experiencing (cases) or not (controls) a defined disease or outcome, and looking at the differences between these groups to define risk factors for the disease/ outcome. By nature, it is a retrospective study design. The study can define more than one case or control type (e.g. case-case-control study). Cases and controls can be matched or not.

- ☐ **Background**
  - Explain the research topic to a non-expert
  - Present prior research, evidence and/ or guidelines on the topic, as relevant
  - Explain the clinical rationale for the current study and the rationale for selecting a case-control design
- ☐ **Objectives and hypothesis** (if relevant)
- ☐ **Study significance**
- ☐ **Study design**: define the study as a case-control study and whether matched or not
- ☐ **Setting and dates**:
  - Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.
  - In studies based on secondary use of data describe the data sources that will be used.

- ☐ **Patients** (Study population)
  - Define cases and controls and the methods of case ascertainment. Provide the inclusion and exclusion criteria for cases and controls and give diagnostic criteria, if applicable.
  - In studies based on secondary use of data the methods of study population selection such as codes or algorithms used to identify subjects, should be listed in detail. If this is not possible, an explanation should be provided.
  - Patient sampling. Define how cases and control were identified and sampled from those potentially eligible; preferably both groups should be drawn from the same population
  - Define matching criteria and case: control ratio, if relevant, and justify the selection of matching variables.
  - explain how matching of cases and controls was addressed

- **Study variables**
  - Independent (or exposure) variable. The exposure variable is the treatment, test or patient characteristic of interest, on which the study hypothesis is based
  - Other study variables, if relevant: confounders, effect modifiers and risk factors for the study outcome, other than the exposure variable. Other descriptive data collected
  - In studies based on secondary use of data a complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided.
- **Data sources**: From where and how will data be collected? For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods of exposure variables for cases and controls if relevant.
- **Sample size or power**. If the sample size is known in advance calculate the power of this sample to answer the study question. Otherwise compute the needed sample size. Discuss the feasibility of reaching the needed sample size supported by relevant data.
- **Statistical analysis.**
  - Describe all statistical methods, including those used to control for confounding. Consider that matching does not control necessarily for confounding and address the methods for adjustment for confounders.
  - Describe any methods used to examine subgroups and interactions
  - Explain how missing data were addressed.
  - In studies based on secondary use of data information on the data cleaning methods used in the study should also be provided.

- **Ethical considerations**
- **Potential sources of bias:** describe the planned study limitations, potential bias and, if relevant, methods to address these.